JUN - 1 2001

K010315

510(k) Summary

[As required by 21 C.F.R. § 807.92 (c)]

January 31, 2001

Submitter's Name:

iScreen, LLC
668 Colonial Road, Suite 1
Memphis, Tennessee 38117
Phone: (901) 888-0071
Fax: (901) 888-0072

Contact Person: Peter Thrall, Chief Operating Officer

Device Trade Name: iScreen Vision Screener

Common Name: Ophthalmic Refractometer/Ophthalmic Camera

Classification Regulations:

Ophthalmic Refractometer – 21 C.F. R. § 886.1760
Ophthalmic Camera – 21 C.F. R. § 886.1120

Legally Marketed Device to Which Equivalence is Claimed:

- MTI Photoscreener (K934880)
- Digital Retinoscopic Photometer (K951179)

Description of the Device:

The iScreen Vision Screener belongs to a generic class of ophthalmic devices that utilize the technique of eccentric photorefraction to record the retinal reflex and ocular status of the eye. All of these instruments have similar primary components: 1) an illumination source, and 2) a recording device. These instruments project a beam of light onto the face and eyes of a patient. The recording device, typically a digital or film-based camera, records an image of the retinal reflex, sometimes called the "red reflex." The retinal reflex provides indications of the ability of the eye to focus light. The ocular status is also recorded in the same image

since any degradation of the optics of the eye that would affect vision will also degrade the beam of light generated by the illumination source.

Similarly, the iScreen Vision Screener system is composed of two parts: 1) a camera unit that records the retinal reflex and ocular status, and 2) a computer that stores the data for later interpretation. The camera unit and computer are powered by a transformer that plugs into a standard 110 VAC wall outlet. The camera unit is supplied with 12 VDC and the computer with 14 VDC. The camera unit is similar to any ophthalmic camera, being comprised of a housing for components, a digital camera for recording the retinal reflex and ocular status, a flash system for generating light, a fixation device for attracting the patient's attention and an alignment camera that helps the user position the patient very accurately. The digital camera is becoming widely used in nearly all aspects of medical imaging. The light source used in this device is a standard photographic flash that is fitted with an attenuator that shapes the beam in to a line of light. The attenuating mask is a small aluminum plate with a 3 mm X 10 mm slot, restricting the output area to roughly 5% of the original. The intensity of light is attenuated to 2.04×10^{-6} W/cm^2, which is much less than standard off-the-shelf photoflash equipment.

Summary of Intended Use:

The iScreen Vision Screener is a tool for screening vision problems in humans. It records and measures the retinal reflex and ocular status, providing data points for analysis and interpretation.

Summary of Technological Characteristics of the iScreen Vision Screener as Compared to the Predicate Devices:

The iScreen Vision Screener is very similar in function and purpose to the MTI Photoscreener (K934880), Digital Retinoscopic Photometer (K951179), and Ophthalmic Refractometer/camera devices. All of these devices use an illumination source and camera to record and measure the retinal reflex and ocular status. The MTI Photoscreener and Digital Retinoscopic Photometer record grayscale images, while the iScreen Vision Screener records a color (24 bit) image. The Digital Retinoscopic Photometer and the iScreen Vision Screener record images with a digital camera, which are subsequently transferred to a computer. The MTI Photoscreener is a film-based system, using a Polaroid™ camera to record information. Both the MTI Photoscreener and iScreen Vision Screener rely on human interpretation of the results of the photoscreening image, whereas the Digital Retinoscopic Photometer uses computer algorithms to measure image parameters.

Both The MTI Photoscreener and iScreen Vision Screener employ a fixation component made up of blinking light emitting diodes (LED's) and an audible sound to attract the patient's attention so that they fixate very close to the camera. The iScreen Vision Screener also uses an infrared camera to assist the user in positioning the patient in a dimly lit room. The use of an infrared camera for patient positioning is not significantly different, and does not affect the primary purpose or function of the device.

The Digital Retinoscopic Photometer and iScreen Vision Screener both use 110VAC as a power source. However, the iScreen Vision Screener employs an in-line transformer so that only 12VDC is supplied to the camera unit and 14VDC to the computer. The MTI Photoscreener is a battery-powered unit.

All eccentric photorefractors are marketed for similar purposes. Since a system employing this technique does not require verbal response from the patient, it can be used to screen patients of all ages for vision problems, and becomes particularly useful for preverbal children.

Safety and Effectiveness Statement

To assure that the device is safe and effective, all finished devices are tested and must meet all required release specifications before distribution. The testing required for release includes, but is not limited to the following:

- Camera
    1. Printed Circuit board
        a. Power distribution to electronic components
        b. Fixation LED's
    2. Wiring harness
    3. Photoflash
        a. Charging circuitry
        b. Intensity
        c. Alignment
    4. Digital camera
        a. Focus
        b. Aperture
        c. Alignment
    5. IR camera
        a. Focus
        b. Alignment
    6. Image quality

7. Mechanical integrity

- Computer
  8. Cabling
  9. Communications with camera device
  10. Software functionality

The required testing is defined by written and approved procedures that conform to the device design specifications.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 1 2001

Mr. Peter Thrall
Chief Operating Officer
iScreen™, LLC
668 Colonial Road, Suite 1
Memphis, TN 38117

Re: K010315
Trade Name: iScreen Vision Screener
Regulatory Class: II
Product Code: HKI
Regulation: 886.1120
Dated: May 1, 2001
Received: May 7, 2001

Dear Mr. Thrall:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-6413. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

A. Ralph Rosenthal

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

510(k) Number (if known): K010315

Device Name: iScreen Vision Screener

Indications For Use:

The iScreen Vision Screener is a tool for screening vision problems in humans. It records and measures the retinal reflex and ocular status, providing data points for analysis and interpretation.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K010315

Prescription Use ✓ OR Over-The-Counter Use_____
(Per 21 CFR 801.109)